



<b>Title:</b>	<b>Standard Operating Procedures for Suspect &amp; Illegitimate Product</b>
<b>Issue Date:</b>	<b>5/2/2015</b>
<b>Effective Date:</b>	<b>5/9/2015</b>
<b>Re-Issue Date:</b>	<b>3/15/2021</b>

**PURPOSE:**

This policy will serve as a guideline to ensure no illegitimate products enter the drug supply chain.

**INSTRUCTIONS:**

Each Safe Chain Solutions employee should have a clear understanding of the proper way to verify a product's legitimacy and the correct handling of suspect products.

**DEFINITIONS:**

1. Illegitimate product means a product for which credible evidence shows that the product:
  - is counterfeit, diverted, or stolen;
  - is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans
  - is the subject of a fraudulent transaction
  - appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.
2. Suspect Products are defined by Section 581 (21) of the FD&C Act as products that are:
  - Potentially counterfeit, diverted, or stolen;
  - Potentially intentionally adulterated such that a the product would result in serious adverse health consequences or death to humans;
  - Potentially the subject of a fraudulent transaction; or
  - Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

**PROCEDURES:**

1. Process to identify suspect products in a timely and efficient manner. This is directly referenced from DSCSA Implementation: Identification.
  - a. New Trading Partner set up.
    - i. Purchasing from a new trading partner
    - ii. Receiving unsolicited sales
    - iii. Purchasing products online from an unknown source
    - iv. Purchasing a product from a source that that is known or suspected to have been involved in transactions of suspect products such as:
      - A trading partner that has bene involved in business transactions where they have sold or delivered suspect or illegitimate products.
      - A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete

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information.

- A trading partner that is reluctant to provide a transaction history or pedigree associated with the product being purchased or does not do so in a timely manner.
- Transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious.